IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Robert F. Rioux, et al.

Serial No.: 10/685,744

Filed: October 14, 2003

For: LIQUID INFUSION APPARATUS FOR RADIOFREQUENCY TISSUE ABLATION

Group Art Unit: 3739

Confirmation No. : 6134

Examiner: Toy, Alex B.

REPLY BRIEF-CFR 41.41

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in reply to the Examiner's Answer dated November 29, 2006. Appellants agree with the statements made in item numbers (1)-(8) of the Examiner's Answer, and respond to the statements made in item numbers (9) and (10) of the Examiner's Answer as follows:

Appellant respectfully disagrees with the Examiner's reasoning for sustaining the rejection of claims 1-4 and 6-15 as being obvious in view of the combination of Edwards

CERTIFICATE OF TRANSMISSION

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below via the USPTO EFS-Web filing system.

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Jocelyn L. Lee

and VanTassel, and to the extent that Edwards and VanTassel are combined with Rangawamy or Kirsch, disagree with the Examiner's reasoning for sustaining the rejection of the remaining claims 5 and 16.

VanTassel Not Analogous Prior Art

The Examiner continues to maintain that any commonality between the claims and a prior art reference satisfies the "field of endeavor" prong of the analogous prior art test. In particular, the Examiner states that the applicant "is unduly limiting the field of applicant's endeavor to not encompass the full scope of the invention" (see page 11, lines 10-11 of Examiner's Answer), apparently meaning that Appellant has not considered every claim element in determining the field of the endeavor. The Examiner then indicated that "applicant is also concerned with the basic field of delivering fluid from a needle into tissue," because "if this were not true, application would not have specified that the needle of independent claims 1 and 10 had to comprise a porous material to allow fluid to flow there through (see page 11, lines 11-16 of Examiner's Answer).

Clearly, the field of endeavor prong of the analogous prior art test cannot be so easily satisfied by finding a claim element in a prior art reference—else there would be no point in performing the analogous prior art test, since commonalities can always be found between a claimed invention and the teachings of a secondary prior art reference that the Examiner wishes to use to obviate the claimed invention. That is, to establish obviousness, an examiner will typically bring in a secondary prior art reference for supplementing a primary prior art reference that fails to disclose one of the claim elements. Thus, if one were to conclude that a secondary prior art reference is

analogous simply because it discloses the missing claim element, there would be no point in performing the analogous prior art test prior to the obviousness test. The fact that the inventors emphasize the significance of a particular claim element, and in this case the "delivery of fluid," simply does not render every prior art reference that discloses fluid delivery analogous prior art to the claimed invention.

The Examiner further stated that "electrode needles that simply deliver fluid are well-known in the art, so it appears that applicant is attempting to define over the prior art by claiming how the needle delivers the fluid—i.e., through the porous material" (see page 11, lines 16-19 of Examiner's Answer). However, the difference between the claimed invention and the prior art is relevant to obviousness—not whether or not a prior art reference is analogous prior art. The fact that fluid-delivering RF ablation needles exist in the prior art simply does not broaden the field of the endeavor of the claimed invention to include all fluid delivery needles. As made clear in the background of the invention, the field of the endeavor of the claimed invention is therapeutic RF ablation of tissue—not the delivery of fluid into tissue.

With respect to the "particular problem" prong of the analogous prior art test, the Examiner indicated that Appellant has unduly limited the scope of the problem with which the inventors were concerned, since "while applicant may be concerned with the ablative treatment of tumors, applicant is also merely trying to uniformly deliver fluid through a needle" (see page 12, lines 10-12 of Examiner's Answer). The Examiner cites page 2, lines 7-15 of the specification to support this conclusion. However, this excerpt merely recognizes that there is a problem of using a separate syringe to inject saline into the tissue to be ablated, because the saline may not be injected into the

target tissue region or only locally within a portion of the target tissue region; that is, there is a recognition of a problem with delivering the saline in the proper region—not a problem of uniformly delivering the saline. The Examiner further cites page 28, line 22 to page 29, line 2 of the specification (i.e., the preferred embodiment of the invention) to further support the conclusion that the inventors were concerned with the problem of delivering fluid in a uniform manner. However, the fact that this citation is located in the detailed description of the preferred embodiment clearly shows that the delivery of saline in a uniform manner is an intermediate solution (with the porous structure being the ultimate solution) to the problem of providing an efficient RF ablation. It is not the ultimate problem that the inventors were attempting to solve.

Notwithstanding the problem with which the inventors were posed, the problem that VanTassel was attempting to solve was not directed to uniformly delivering fluid through a needle. Rather, the problem addressed by VanTassel was the prevention of the rapid transfer of medicament (see col. 2, lines 18-32), with the uniform delivery of the medicament through a porous needle being the solution.

The problem with the Examiner's characterization of VanTassel as being analogous is that one of ordinary skill in the art would have to be specifically pointed to VanTassel to even determine that it is related to RF tissue ablation and any problems associated therewith. The Federal Circuit has stated:

> [I]t is necessary to consider "the reality of the circumstances"—in other words, common sense—in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventors. In re Oeitker at 1447 (emphasis in original).

In the present case, one of ordinary skill in the art attempting to solve the problem of providing a more efficient tissue ablation (with or without fluid delivery) would simply not

look to prior art related to prior art references directed to solving problems related to the delivery of a medicament.

Any Suggestion to Modify Edwards in View of VanTassel is Lacking

The Examiner has stated that "applicant has unduly limited the nature of the problem to be solved by Edwards and VanTassel," and by doing this, the "applicant has overlooked that it is not necessary for the needle of VanTassel to ablate tissue in order to provide motivation to make the needle of Edwards from a porous material" (see page 13, lines 1-5 of Examiner's Answer). It may not be necessary for the needle of VanTassel to ablate tissue, but it is necessary for VanTassel to provide some explicit or inherent suggestion to modify the RF ablation needle of Edwards. The Examiner, in essence, concludes that because both Edwards and VanTassel are directed to delivering fluid through a needle, then there must be some suggestion to combine their teachings (see page 13, lines 6-17 of Examiner's Answer). However, the fact that both references discuss fluid delivery does not amount to a suggestion.

VanTassel is directed to the delivery of medicament, and discloses the use of a porous needle to prevent the fast delivery of medicament into tissue. Although a more uniform distribution of the medicament may result from the VanTassel device, there is no teaching in VanTassel that a more uniform distribution of a fluid can be advantageous in any device other than one that delivers medicament. Nor is there any teaching in Edwards that a more uniform distribution of fluid to provide a more efficient ablation is desirable. Such disclosure can only be derived from the present application, which the Examiner cannot use to provide the suggestion to combine Edwards and VanTassel.

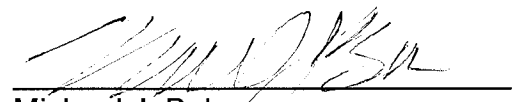
Essentially what the Examiner has done is use Appellant's specification to connect the disparate teachings of Edwards and VanTassel. While the Examiner has states that no hindsight reconstruction was used as a basis for the obviousness rejection, Appellant strongly believes that, without the teachings of the specification, there is simply no suggestion to combine Edwards and VanTassel. That is, the prior art identified by the Examiner includes the use of a separate needle to deliver saline to facilitate tissue ablation (background of application), an RF ablation needle that delivers saline to facilitate tissue ablation (Edwards), and a porous needle for delivering medicament to tissue in a controlled manner (VanTassel). Without using Appellant's disclosure, there is no suggestion or motivation to combine this prior art in a manner that results in the claimed invention.

For the above reasons, Appellant believes that the Examiner's rejections of claims 1-16 should be overturned.

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: January 29, 2007

By: 
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